160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Diagnosis and Treatment of Tethered Spinal Cord

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Diagnosis and Treatment of Tethered Spinal Cord,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E77D

Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Kelly Carper, Telephone: 301-427-1656 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Diagnosis and Treatment of Tethered Spinal Cord.* AHRQ is conducting this review pursuant to section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Diagnosis and Treatment of Tethered Spinal Cord*. The entire research protocol is available online at: https://effectivehealthcare.ahrq.gov/products/tethered-spinal-cord/protocol

This is to notify the public that the EPC Program would find the following information on *Diagnosis and Treatment of Tethered Spinal Cord* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.

        - *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements, if relevant: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
    - *A list of ongoing studies that your organization has sponsored for this topic*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
    - Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/email-updates.

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1: What is the accuracy of radiographic and other diagnostic criteria in diagnosing tethered spinal cord?

KQ 2: What are the benefits and harms of prophylactic surgery for asymptomatic tethered spinal cord patients?

KQ 3: What are the effectiveness, comparative effectiveness and harms of surgical and non-surgical treatments for symptomatic tethered spinal cord?

a. Stratified by symptom type, intensity, and patient age?

b. Are effects modified by use of special surgical equipment or techniques?

KQ 4: Among individuals who experience retethering after spinal detethering surgery, what are the benefits, harms and long-term outcomes of another surgery compared with no treatment?

a. Are individual factors with which a patient presents (such as primary symptoms, symptom intensity, age, etc.) associated with better or worse outcomes after repeat surgery?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

Table 1. Eligibility Criteria

Element	Inclusion Criteria	Exclusion Criteria
Population	KQ1: Pediatric or adult patients assessed for tethered spinal cord KQ2: Pediatric or adult patients with tethered spinal cord and no symptoms or marginally symptomatic without functional deficits KQ3: Pediatric or adult patients with symptomatic tethered spinal cord KQ4: Pediatric or adult patients who experience retethering after spinal detethering surgery	Tethering of the spine as an adverse event associated with an intervention (not patients being treated for tethered spinal cord)
Interventions	KQ1: Screening and diagnostic approaches, tools, and criteria such as physical examination, urodynamic studies, (MRI), myelogram, computed tomography (CT) scan, computed axial tomography (CAT) scan, or ultrasound KQ2: Prophylactic or early surgery	Interventions and approaches not addressing tethered spinal cord

Element	Inclusion Criteria	Exclusion Criteria
	KQ3: Surgical or non-surgical treatment or management interventions such as surgical detethering, or other surgery (e.g., spine-shortening vertebral osteotomy, spinal cord transection), physical therapy, bladder therapy for bladder function, or bracing KQ4: Surgical interventions such as repeat detethering, revision detethering, spine-shortening vertebral osteotomy, vertebral column shortening, spinal cord transection, or other surgery	
Comparators	KQ1: Confirmation of diagnosis by a neurosurgeon or neurologist KQ2-4: No surgery, sham surgery, no treatment, or alternative treatments for effectiveness outcomes; no comparator is required for studies reporting adverse events of interest (eligible adverse events will be determined with the help of the TEP)	KQ 1: no comparator For KQ 2-4, Studies without comparator except for studies for an adverse event of interest
Outcomes	KQ1: Diagnostic performance (e.g., diagnostic accuracy measured as concordance with neurosurgeon or neurologist diagnosis); adverse events of the diagnostic procedure; and clinical impact of a correct or incorrect diagnosis such as (e.g., overtreatment due to misdiagnosis, delayed treatment, or undertreatment due to missed diagnosis) KQ2-4: Patient health and other patient effects such as leg weakness, leg numbness, leg pain, other pain, gait, walking difficulty, bowel incontinence, bladder incontinence, scoliosis, disability, adverse events, postoperative complications, infection, 30-day complication rate, morbidity, quality of life, or general health status, as well as process measures such as repeat surgery	Provider satisfaction and frequency of procedures
Timing	No restrictions regarding the timing or duration of the intervention or the follow up	N/A
Setting	Settings compatible with US healthcare settings, no restrictions regarding the clinical setting	Very low resource countries or conflict zones
Study Design	KQ1: Diagnostic accuracy and diagnostic impact analyses KQ2-4: Randomized controlled trials (RCTs), clinical trials without randomization, cohort studies comparing two cohorts, controlled post-only studies, and case-control studies. Experimental single arm trials and observational case series, with or without structured pre- and post-intervention data, need to report on neurological status or bladder or bowel function to be eligible.	Secondary data, but systematic reviews will be retained for reference-mining
Other limiters	Data published in journal manuscript and trial records	Data reported in abbreviated format (e.g., conference abstracts)

Note: KQ key question, TEP technical expert panel

Dated: August 29, 2023.

Marquita Cullom,

Associate Director.

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